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DC-20-04477

CAUSE NO. _____

BRENDA SHAFFER, RONALD CLEMONS, JERRY WATKINS, JAMAUN RANSOM, ALAN FRAILICH, NANCY POFF, LEROY MOTON, DONALD YOUNG, CHERYL JONES-LATIMER, and IDA NAPOLITANO Plaintiffs, vs. C.R. BARD, INC., BARD PERIPHERAL VASCULAR, INC. MCKESSON CORPORATION,and DOES 1 THROUGH 100 INCLUSIVE Defendants.	IN THE DISTRICT COURT JURY TRIAL DEMANDED 101ST _____ JUDICIAL DISTRICT DALLAS COUNTY, TEXAS

PLAINTIFFS' ORIGINAL PETITION

Plaintiffs, Brenda Shaffer, Ronald Clemons, Jerry Watkins, Jamaun Ransom, Alan Frailich, Nancy Poff, Leroy Moton, Donald Young, Cheryl Jones-Latimer, and Ida Napolitano by and through the undersigned counsel, file this Petition and Jury Demand, and allege upon information and belief as follows:

DISCOVERY

1. Pursuant to Rule 190 *et seq* of the Texas Rules of Civil Procedure, Plaintiffs request Level III discovery control plan.

INTROUDCTION

2. Brenda Shaffer, Ronald Clemons, Jerry Watkins, Jamaun Ransom, Alan Frailich, Nancy Poff, Leroy Moton, Donald Young, Cheryl Jones-Latimer, and Ida Napolitano (hereinafter "Plaintiffs,") for their Petition, alleges:

PARTIES

3. Brenda Shaffer is, and was at all times material herein, a resident of Gainesville, Cooke County, Texas.

4. Ronald Clemons is, and was at all times material herein, a resident of Kansas City, Wyandotte County, Kansas.

5. Jerry Watkins is, and was at all times material herein, a resident of Irvine, Estill County, Kentucky.

6. Jamaun Ransom is, and was at all times material herein, a resident of Paris, Bourbon County, Kentucky.

7. Alan Frailich is, and was at all times material herein, a resident of Henderson, Clark County, Nevada.

8. Nancy Poff is, and was at all times material herein, a resident of Homestead, Miami-Dade County, Florida.

9. Leroy Moton is, and was at all times material herein, a resident of Hartford, Hartford County, Connecticut.

10. Donald Young is, and was at all times material herein, a resident of West Warwick, Kent County, Rhode Island.

11. Cheryl Jones-Latimer is, and was at all times material herein, a resident of Kingman, Mohave County, Arizona.

12. Ida Napolitano is, and was at all times material herein, a resident of Old Saybrook, Middlesex County, Connecticut.

13. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the State of Delaware and has its principal place of business in New Jersey. Bard at all times relevant to this action, designed, set specifications, marketed, distributed, and sold the Bard Filter to be implanted within patients throughout the United States.

14. Defendant Bard Peripheral Vascular, Inc., ("BPV") is a wholly owned subsidiary corporation of Defendant Bard, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona. BPV at all times relevant to this action, designed, set, specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Bard Filter to be implanted in patients throughout the United States.

15. Defendant McKesson Corporation ("McKesson") is a Delaware Corp with its principal place of business located in Dallas county Texas.

16. At all times relevant to this Petition, McKesson was engaged in the business of licensing, distributing, selling, marketing and/or providing health information technology, medical supplies, and care management tools into interstate commerce, either directly or indirectly through third parties or entities throughout Rowlett, Dallas County, Texas and surrounding cities, as well as throughout the United States. McKesson's business included designing, launching, marketing, establishing, and administering the Bard Reach™, a marketing initiative designed to ensure patients implanted with Bard IVC filters are tracked for follow up care or retrieval of the filter. On information and belief, Defendant McKesson marketed the Bard Filters with which the Plaintiffs were each implanted.

17. All references to "Defendants" hereafter shall refer to Defendants Bard, BPV, McKesson, and DOES 1 through 100.

18. The true names, identities, or capacities, whether individual, associate, corporate or otherwise of defendants, DOES 1 through 100, are unknown to Plaintiffs who, therefore, sues said Defendants by such fictitious names. When the true names, identities or capacities of said fictitiously designated Defendants are ascertained, Plaintiffs will seek leave of the Court to amend this Petition to insert the true names, identities, and/or capacities of DOE Defendants, together with the proper charging allegations against said DOE Defendants.

19. Plaintiffs are informed and believes and thereon alleges that each of the Defendants sued herein as a DOE Defendant is responsible in some manner for the acts, omissions, and conduct, which proximately resulted in and/or was a substantial contributing factor in Plaintiffs' injuries.

20. Upon belief, all fictitious Defendants were residents of the County of Maricopa, State of Arizona; and/or were organized and existing under the laws of Arizona and doing business throughout the United States, and conducting business therein on the date of the accident alleged herein.

JURISDICTION AND VENUE

21. At all relevant times, each Defendant transacted, solicited, and conducted business in Dallas County, in the State of Texas, and derived substantial revenue from such business.

22. At all relevant times, each Defendant expected or should have expected that its acts would have consequences within the United State of America and the State of Texas.

23. Venue is proper in Dallas County, Texas, because all or a substantial part of the events or omissions giving rise to this claim occurred in Dallas County, Texas. TEX. CIV. PRAC. & REM. CODE §15.002(a)(1). In addition, venue is proper in Dallas County, Texas, because Defendant McKesson Corporation's principal office in Texas is located in Irving, Dallas County, Texas. TEX. CIV. PRAC. & REM. CODE §15.002(a)(3).

24. Plaintiffs' claims are with the jurisdictional limits of the Court. Plaintiffs' seek monetary relief over $1,000,000. Tex. R. Civ. P. 47.

25. This Court has subject-matter jurisdiction over this lawsuit because the amount in controversy exceeds this Court's minimum jurisdictional requirements. TEX. GOVT. CODE §24.007(b).

26. "The Court has personal jurisdiction over Defendant McKesson Corporation because its national corporate headquarters and principal place of business is located in Irving, Dallas County, Texas, and because Plaintiff Brenda Shaffer is a resident of the State of Texas."

27. The Court has personal jurisdiction over each Defendant because each Defendant committed a tort in whole or in part in the State of Texas. TEX. CIV. PRAC. & REM. CODE §17.042(2).

28. Each Defendant marketed, advertised, and distributed Bard Filters in the State of Texas. The Court has personal jurisdiction over each Defendant because each Defendant purposefully availed itself of the privileges and benefits of conducting business in Texas by marketing, advertising, selling, and distributing products in the State of Texas.

29. Defendant McKesson Corporation is a citizen of the State of Texas by virtue of its maintenance of its principal place of business in Irving, Dallas County, Texas. Each other Defendant purposefully availed itself of the State of Texas by *inter alia* contracting with McKesson Corporation to distribute the Bard Filters. Each Defendant would suffer minimal or no inconvenience litigating this matter in the State of Texas, which is a convenient location. Traditional notions of fair play and substantial justice are in no way compromised by maintenance of these claims in the State of Texas

GENERAL FACTUAL ALLEGATIONS

30. Upon information and belief, Defendants have designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold many iterations of inferior vena cava filters, including but not limited to, Recovery® Filter, G2® Filter, G2X® Filter, Eclipse® Filter, Meridian® Filter, and the Denali® Filter. Plaintiffs bring this action after being implanted with one of Defendants inferior vena cava filters, herein referred to as "Bard Filter" or "Bard Filters".

31. Plaintiffs bring this case for serious personal injuries suffered as a result of being surgically implanted with one of Defendants Bard Filters.

32. The Bard Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and/or sold by for the prevention of blood clots (thrombi) from travelling from the lower portions of the body to the heart and lungs by Defendants.

33. Prior to Plaintiffs being implanted with a Bard Filter, Defendants knew and/or should have known that the device was defective and unreasonably dangerous for, inter alia, the following reasons:

a. Defendants failed to conduct any clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the Bard Filter had high rates of fracture, migration, and excessive tilting and perforating the vena cava wall once implanted in the human body. Defendants knew and/or should have known that such failures exposed patients to serious injuries, including: death, hemorrhage, cardiac/pericardial tamponade, cardiac arrhythmia and other symptoms similar to myocardial infarction, severe and persistent pain, perforations of tissue, vessels and organs, and inability to remove the device. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device. Further, Defendants knew or should have known that these risks for the Bard Filter were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the Bard Filter contained conditions, which Defendants did not intend, which resulted in the device not performing as safely and the ordinary consumer would expect.

d. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

e. Even when Defendants designed and began marketing what they alleged to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer device was available.

INFERIOR VENA CAVA FILTERS GENERALLY

34. Inferior vena cava ("IVC") filters first came on to the medical marketed in the 1960's. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

35. An IVC Filter is a device that is designed to filter or catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the inferior vena cava—the largest vein in the human body.

36. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvic, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present risks to human health. They can, and often do, result in death.

37. Certain people are at an increased risk for the development of DVT or PE. For instance, someone who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at an increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE, including "coagulopathies" and clotting disorders

38. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

39. As stated above, IVC filters have been on the market for decades. The first IVC filters marketed were permanent filters. These devices were designed to be left in a patient's IVC permanently and have long-term follow-up data (of up to 20 years and longer) supporting their use and efficacy. Beginning in 2003, manufacturers also began marketing what are known as optional or retrievable filters. These filters are designed so they can be surgically removed from a patient after the risk of PE has subsided. These IVC filter designs, however, were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery® Filter System, the subsequent G2® Filter, G2X® Filter, Eclipse® Filter, Meridian® Filter, and Denali® Filter System, manufactured by Bard and BPV are all examples of retrievable filters. As shown below, Bard's retrievable IVC filters have been plagued with problems – all created by Bard and BPV.

40. As recently as October 2015, an expansive article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually caused thrombi to occur.

41. Comparing the results of over 30,000 trauma patients who had not received IVC filters with those who had received them, the *Annals of Surgery* study published its alarming results:

a. Almost twice the percentage of patients with IVC filters in the study died compared to those that had not received them;

b. Over five times the relative number of patients with IVC filters developed DVTs;

c. Over four times the relative percentage of patients with filters developed thromboemboli;

d. Over twice the percentage of patients developed a pulmonary embolism – the very condition Bard and BPV told the FDA, physicians, and the public that its IVC filters were designed to prevent.

42. This *Annals of Surgery* study – and many others referenced by it – now shows without any question that IVC filters are not only utterly ineffective but that they are themselves a health hazard.

THE RECOVERY FILTER

FDA Clearance and Intended Use

43. Bard has sold several models of IVC filter, including but not limited to the Recovery Filter, the G2 Filter, the G2 Express Filter, the Eclipse Filter, and the Denali Filter. Bard began sales of the Recovery Filter in 2003, and each of the subsequently listed models above are substantially similar to the Recovery Filter. In seeking 510(k) clearance from the FDA—which permits companies to sell medical devices that are substantially similar to predicate devices without substantial clinical testing—Bard has listed the aforementioned devices as predicate devices in their 510(k) applications. Each of the aforementioned devices has been wrought with safety issues. The safety issues in the predicate devices must be understood in order to fully explain the safety issues with the Bard.

44. In 2002, Bard and BPV submitted a notification of intent to the FDA to market the "Recovery® Filter System" (hereafter "Recovery®" or "Recovery® Filter") for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava. On November 27, 2002, the FDA cleared the Recovery® Filter for marketing and use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations: (a) pulmonary thromboembolism when anticoagulants are contraindicated; (b) failure of anticoagulant therapy for

thromboembolic disease; (c) emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and (d) chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

45. In April 2003, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the Recovery ® Filter for the additional intended used of optional retrieval. The FDA cleared this additional intended use on July 25, 2003.

46. Bard and BPV began actually marketing the device in April 2003, but did not begin full market release until 2004. Bard and BPV were aware that the Recovery® Filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric procedures.

What Is It and How Is It Used

47. The Recovery Filter consists of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter in the inferior vena cava and to catch an embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" within the vena cava and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism".

48. As noted above, the Recovery® Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL possesses "shape memory". That is, NITINOL will change shape according to changes in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter

catheter. The metal struts then reassume their original shape when warmed to body temperature inside the vena cava.

49. The Recovery® Filter is inserted by a catheter that is guided by a physician through a blood vessel into the inferior vena cava. The Recovery® Filter is designed to be retrieved in a similar fashion. The implanting physician normally reviews an imaging study prior to placement to determine the size of the IVC, renal vein location, and to identify any venous anomalies or clots in the vena cava. Following placement, the physician will normally use an imaging study to confirm successful placement.

Inherent Risks of the Recovery® Filter

50. The Recovery® Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's Recovery® Filter to have a fracture and migration rate ranging from 21% to 31.7%. When such failures occur, shards of the device, or the entire device, can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to locations, such as the lungs, such that they are too dangerous to remove. These patients are exposed to a lifetime of future risk.

51. The Recovery® Filter failures described above occur at a substantially higher rate than with other IVC filters.

52. The Adverse Event Reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters are fare more prone to device failure then are other similar devices. A review of the FDA MAUDE database from the years 2004-2010 reveals data to establish that Bard's IVC Filters are responsible for the following percentages of all AERs:

a. 50% of all adverse events

b. 64% of all occurrences of migration of the device

c. 69% of all occurrences of vena cava wall perforation

d. 50% of all occurrences of filter fracture.

53. These failures attributable, in part, to the fact that the Recovery® Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

54. In addition to design defects, the Recovery® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the device while in vivo. In particular, the Recovery® Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the Recovery® Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

What Bard and BPV Knew or Should Have Known

55. Bard and BPV knew that no clinical testing, such as animal studies, were conducted to determine whether the Recovery® Filter would perform safely once implanted in the human body and subjected to normal in vivo stresses.

56. Soon after the Recovery® Filter's introduction to the market in 2003, Bard and BPV began receiving large numbers of adverse event reports ("AERs") from healthcare providers reporting that the Recovery® Filter was fracturing post-implantation and that fractured pieces, and/or the entire device was migrating throughout the human body, including to the heart and lungs. Bard and BPV also received a large number of AERs reporting that the Recovery® Filter was found to have excessively tiled and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain;

f. And perforation of tissue, vessels, and organs.

57. Within the first year of full market release of the Recovery® Filter, Bard and BPV received at least 32 AERs reporting that the Recovery® Filter had fractured in vivo and at least 22 AERs reporting that the entire device had migrated in vivo. Of the 22 reported migration failures, at least nine (9) were reported to have been associated with patient death.

58. From 2003 through September 2005, Bard and BPV received ever growing numbers of AERs reporting the above described failures and patient injuries. Defendants knew or should have known that the failure rates associated with the Recovery® Filter were substantially higher than other similar products on the market.

59. Bard and BPV were well aware of why the Recovery® filter was failing and had available design changes to help reduce the failure rate.

60. The diameter of the hooks on the Recovery® filter had been reduced which had reduced the devices ability to remain stable and not fracture.

61. Bard and BPV were also aware that failing to electropolish the wire material prior to distribution meant that the Recovery® Filter would be exposed to surface damage meaning a reduction on the fatigue resistance of the filter.

62. A few examples of Defendants awareness of the unreasonably dangerous problems with Bard IVC filters include:

a. On June 18, 2003, BPV engineer Robert Carr sent an email noting that chamfering the edge of the cap would reduce the likelihood of fracture;

b. On March 16,2004, a BPV engineer sent an email admitting that the surface damage seen on the Recovery® from the manufacturing process decreases fatigue resistance and that electropolishing increases fatigue resistance;

c. In an April 2004 meeting, BPV was warned by its physician consultants, Drs. Venbrux and Kaufman that the migration resistance of the Recovery® filter needed to be raised from 50 mmHg to 140 mmHg. They further warned BPV that Bard's Recovery® filter was a "wimpy" filter and its radial force was inadequate to assure stability;

d. On May 5, 2004, a BPV engineer sent an email stating that adding a "chamfer" to the filter would "address the arm fracture issue;

e. On May 26, 2004, a BPV engineer sent an email stating that a proposed modified Recovery® filter design with a large chamfer lasted 50 bending cycles before breaking, whereas another proposed modified Recovery® filter with a small chamfer broke after ten bending cycles.

Market Withdrawal, but no Recall

63. In late 2004 or early 2005, Bard and BPV, without notifying consumers of the design and manufacturing flaws inherent in the Recovery® Filter, began redesigning the Recovery® Filter in an attempt to correct those flaws. The redesigned filter is known as the G2® Filter, which stands for Second Generation Recovery® Filter.

64. On August 10, 2005, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the G2® Filter for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava. Bard and BPV cited the Recovery® Filter as the substantially equivalent predicate device. Bard and BPV stated that the differences between the Recovery® Filter and the G2® Filter were primarily dimensional and no material changes or

additional components were added. On August 29, 2005, the FDA cleared the G2® Filter for the same intended uses as the Recovery® Filter, except that it was not cleared for retrievable use.

The 510(K) Process Insufficiency

65. Defendants sought Food and Drug Administration ("FDA") approval to market the [insert product name] and/or its components under Section 510(k) of the Medical Device Amendment.

66. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

67. In Medtronic, Inc. v. Lohr, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed

> without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

Recovery® Cone System

68. The market appeal for the Recovery® Filter was the ability to retrieve the filter once the filter had served its purpose. According to the Instructions for Use, only the Recovery® Cone System could be used to retrieve the Recovery® Filter (as well as all subsequent generations of Defendants IVC Filters).

69. The Recovery® Cone System is an independent medical device requiring approval by the FDA under the pre-market approval process or, if a substantially equivalent medical device was already on the market, clearance by the FDA pursuant to the 510(k)-application process.

70. Although Bard and BPV marketed and sold the Recovery® Cone System separately, it never sought or obtained approval or clearance from the FDA for this device.

71. Defendants sale of the Recovery® Cone System was, therefore, illegal.

72. Defendants illegally sold the Recovery® Cone System in order to promote the Recovery® filter (as well as subsequent retrievable IVC filters) as having a retrievable option.

73. On July 12, 2015, the FDA sent a letter to Bard informing them of the marketing without clearance or approval as required by Federal Food, Drug, and Cosmetic Act. Due to the nature of the Recovery® Cone System, Defendants were required to submit a pre-market notification to the FDA and by failing to do so, were in direct violation of section 510(k), 21 U.S.C. 360(k), and 21 C.F.R. 807.81(a)(3)(ii).

74. The letter continues on that in an inspection of the C.R. Bard Inc. facility located at 289 Bay Rd, Queensbury, NY was not in compliance with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. This section relates to the manufacturing, packing, storage, or installation of these devices were not in conformity with the Code suggesting that the devices were subject to manufacturing defects.

THE G2® FILTER

75. Bard and BPV marketed the G2® Filter as having "enhanced fracture resistant", "improved centering", and "increasing migration resistance". However, Bard and BPV again failed to conduct adequate clinical testing, such as animal studies, to ensure that the device would perform safely and effectively once implanted in the human body and subjected to in vivo stresses. Not surprisingly, the G2® Filter's design causes it to be of insufficient integrity and strength to withstand normal in vivo body stresses within the human body so as to resist fracturing, migrating, titling, and/or perforating the inferior vena cava.

76. Also, like its predecessor, in addition to design defect, the G2® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2® Filter in vivo. In particular, the G2® Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2® Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

77. Thus, the G2® Filter shares the same defects and health risks as its predicate device.

78. As with the Recovery® Filter, Bard and BPV immediately began receiving large numbers of AERs reporting that the G2® Filter was, inter alia, fracturing, migrating, excessively tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patients injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain;

f. And perforation of tissue, vessels, and organs.

79. Defendants represent the fracture rate of the G2® Filter to be 1.2%. Based upon a review of the data available in the public, this representation does not accurately reflect the true number of incidences of device fracture for the G2® Filter.

80. A review of the MAUDE database from the years 2005-2010 reveals data to establish that the Bard and BPV's vena cava filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters.

BARD AND BPV'S KNOWLEDGE OF THE RISK OF FAILURE AND RESULTING DANGERS

81. Upon information and belief, Plaintiffs allege that as early as 2003, Bard and BPV were aware and had knowledge of the fact that the Recovery® Filter was defective and unreasonably dangerous and was causing injury and death to patients who had received it. Due to the similarities of the filters, Defendants Bard and BPV were aware that all the subsequent Bard Filters were defective and unreasonably dangerous for they were causing injury and death to patients who had received it.

82. Data establishes that the failure rates of the Bard Filter is/was exceedingly higher than the rate that Bard and BPV have in the past and currently continue to publish to the medical community and members of the public. Further, Bard and BPV were aware or should have been aware that the Bard Filter has substantially higher failure rates than do other similar products on the market, yet Bard and BPV have failed to warn consumers of this fact.

83. From the time the Bard Filter became available on the market, Defendants Bard and BPV embarked on an aggressive campaign of "off label marketing" concerning the Bard Filter. This included representations made to physicians, healthcare professionals, and other members of the medical community that the Bard Filter was safe and effective for retrievable use prior to the FDA approving the Bard Filter for retrievable use.

84. In a letter from the FDA to CEO Timothy M. Ring of C.R. Bard Inc., on July 13, 2015, it was detailed how Defendants had failed to establish and maintain procedures for complaints related to their products:

> Your current procedures governing complaint investigation activities, (b)(4) Standard for Product Complaint Handling (b)(4), Standard for Complaint Investigation Process (b)(4), Complaint Investigation Activity (b)(4), BPV Complaint Handling System, (b)(4), and (b)(4), Complaint Investigation Procedures, (b)(4) do not include adequate instructions for ensuring that complaints involving a device or device component provided by a supplier are adequately evaluated for root cause of the alleged device failure and that appropriate corrective action is implemented with your suppliers. Complaint (b)(4) for a G2 Filter, embolization of a detached filter arm with associated areas of hemorrhage and necrosis in the right lung was filed as a malfunction Medical Device Report [MDR] and should have been filed as a death. The following Complaints were filed as malfunctions and should have been filed as serious injuries: Complaint (b)(4), Eclipse Filter, detached filter limb resulting in pericardial effusion and cardiac catheterization; (b)(4), G2 Express Filter, broken filter and surgical intervention; (b)(4), Denali Jugular System, detached filter arm embedded in IVC wall with filter retrieval; (b)(4), G2 Filter, detached filter limb in renal vein with IVC wall perforation and blood thinner treatment; (b)(4), G2 Express Filter, IVC perforation and aneurysm; (b)(4), G2 Filter, abdominal pain with filter legs protruding through

> IVC wall and percutaneous removal; (b)(4), G2 Filter, abdominal pain with filter legs perforating IVC wall, partial retrieval and residual filter leg fragment embedded in IVC wall. Complaints (b)(4) and (b)(4) report at least 10 patients who were exposed to scheduled retrieval surgical procedures to remove an IVC filter that were not successful. However, these complaint files do not document sufficient information to allow for adequate complaint investigation and disposition, including, but not limited to, MDR determination. For example, the complaints do not include information regarding prolonged or repeated surgery that may have occurred as a result of failed attempts to remove the filters, information regarding why the filters were scheduled to be removed and potential complications related to leaving them in the patient due to failed removal, and/or if any additional drugs or anesthetics had to be supplied to the patients.

85. The letter also charges Bard and BPV with failure to ensure compliance with their specified requirements:

> Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. In particular, 21 CFR 820.50(a) requires that each manufacturer establish and maintain requirements, including quality requirements, that must be met by suppliers, contractors, and consultants.

86. The FDA went on to note that Bard did indeed respond to these allegations from the FDA, but their responses were in fact inadequate as to several of the allegations.

87. The conduct of Bard and BPV as alleged in this Petition constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of the Plaintiffs or their healthcare providers. Bard and BPV had actual knowledge of the dangers presented by the Bard Filter, yet consciously failed to act reasonably to:

a. Inform or warn Plaintiffs, their physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Bard Filter from the market.

88. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the Bard Filter, Bard and BPV consciously disregarded the known risks and continued to actively market and offer for sale the Bard Filter.

89. Plaintiffs further allege that Bard and BPV acted in willful, wanton, gross, and total disregard for the health and safety of the users or consumers of their Bard Filter, acted to serve their own interests, and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

SPECIFIC FACTUAL ALLEGATIONS AS TO BRENDA SHAFFER

90. Plaintiff Brenda Shaffer was implanted with a Bard G2® Filter on or about January 6, 2009 at Wilson N. Jones Medical Center in Sherman, Texas. The filter was implanted after being diagnosed with thromboembolic disease with a recent pulmonary embolus.

91. This G2® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

92. On or about January 21, 2020, Ms. Shaffer underwent a CT Scan at Akumin Preferred Imaging in Denton, Texas. Upon information and belief, the scan revealed that the filter struts perforated through theIVC wall coming in close proximity to the soft tissue and bony structures.

SPECIFIC FACTUAL ALLEGATIONS AS TO RONALD CLEMONS

93. Plaintiff Ronald Clemons was implanted with a Bard Denali® Filter on or about 9/12/2014 at Univeristy of Kansas Hospital in Kansas City, Kansas by Dr. Ben Maertins. The filter was implanted due to Mr. Clemons' elevated risk of developing deep vein thrombosis and/or incur a pulmonary embolic event post-bariatric surgery.

94. This Denali® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

Upon information and belief, Plaintiff Ronald Clemons has suffered, is suffering, and will continue to suffer fear of future potential complications and injuries that can be connected to the implantation of Defendant's Bard Filter.

SPECIFIC FACTUAL ALLEGATIONS AS TO JERRY WATKINS

95. Plaintiff Jerry Watkins was implanted with a Bard Eclipse® Filter on or about 7/25/2011 at Saint Joseph Hospital in Lexington, Kentucky by Dr. Jason Harper.

96. The Eclipse® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

97. Upon information and belief, Plaintiff Jerry Watkins has suffered, is suffering, and will continue to suffer fear of future potential complications and injuries that can be connected to the implantation of Defendants' Bard Filter.

SPECIFIC FACTUAL ALLEGATIONS AS TO JAMAUN RANSOM

98. Plaintiff Jamaun Ransom was implanted with a Bard Denali® Filter on or about March 28, 2014 at University of Kentucky Hospital in Lexington, Kansas. The filter was implanted due to Mr. Ransom being diagnosed with deep vein thrombosis and subsequent pulmonary embolism with anticoagulation being ineffective.

99. The Denali® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

Upon information and belief, Plaintiff Jamaun Ransom has suffered, is suffering, and will continue to suffer fear of future potential complications and injuries that can be connected to the implantation of Defendants' Bard Filter.

SPECIFIC FACTUAL ALLEGATIONS AS TO ALAN FRAILICH

100. Plaintiff Alan Frailich was implanted with a Bard Denali® Filter on or about August 25, 2015 at St. Rose Dominican Hospital-Siena Campus in Henderson, Nevada by Dr. Brian E. Lee. The filter was implanted due to Mr. Frailich's being diagnosed with deep vein thrombosis and subsequent hemoptysis.

101. This Denali® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

102. Upon information and belief, Plaintiff Alan Frailich has suffered, is suffering, and will continue to suffer fear of future potential complications and injuries that can be connected to the implantation of Defendants' flawed Bard Filter.

SPECIFIC FACTUAL ALLEGATIONS AS TO NANCY POFF

103. Plaintiff Nancy Poff was implanted with a Bard Meridian® Filter on or about December 18, 2013 at Duke Medicine in Durham, North Carolina by Amar M Amaresh.The filter was implanted due to Ms. Poff being diagnosed with deep vein thrombosis and subsequent pulmonary embolism.

104. The implanted Meridian® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

Upon information and belief, Plaintiff Nancy Poff has suffered, is suffering, and will continue to suffer fear of future potential complications and injuries that can be connected to the implantationof Defendants' Bard Filter.

SPECIFIC FACTUAL ALLEGATIONS AS TO LEROY MOTON

105. Plaintiff Leroy Moton was implanted with a Bard Eclipse® Filter on or about May 5, 2014 at Lenox Hill Hospital in New York City, New York by Dr. Alfio Carroccio. The filter was implanted due to Mr. Moton's being diagnosed with deep vein thrombosis with anticoagulation being ineffective.

106. This Eclipse® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

107. Upon information and belief, Plaintiff Leroy Moton has suffered, is suffering, and will continue to suffer fear of future potential complications and injuries that can be connected to the implantationof Defendants' flawed Bard Filter.

SPECIFIC FACTUAL ALLEGATIONS AS TO DONALD YOUNG

108. Plaintiff Donald Young was implanted with a Bard G2® Filter on or about June 13, 2008 at Rhode Island Hospital in St. Providence, Rhode Island by Gregory Soares M.D. The filter was implanted as a result of Mr. Young being diagnosed with deep vein thrombosis and subsequent pulmonary embolism with anticoagulation being ineffe

109. This G2® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

110. Upon information and belief, Plaintiff Donald Young has suffered, is suffering, and will continue to suffer fear of future potential complications and injuries that can be connected to the implantation of Defendants' flawed Bard Filter.

SPECIFIC FACTUAL ALLEGATIONS AS TO CHERYL JONES-LATIMER

111. Plaintiff Cheryl Jones-Latimer was implanted with a Bard Denali® Filter on or about August 27, 2015 at Kingman Regional Medical Center, Kingman, AZ by Dr. Ismail Bokhari. The filter was implanted due to Ms. Jones- Latimer being diagnosed with deep vein thrombosis and a preventive measure before surgery.

112. This Denali® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

113. On or about October 12, 2018, Ms. Jones-Latimer underwent a CT scan in order to evaluate her Denali® Filter at Comprehensive Cancer Centers of Nevada. Upon information and

belief, the scan revealed that the Denali® Filter had become embedded in the inferior vena cava wall and was deemed to not be retrievable due to this complication.

SPECIFIC FACTUAL ALLEGATIONS AS TO IDA NAPOLITANO

114. Plaintiff Ida Napolitano was implanted with a Denali® Filter on or around June 4, 2018, at Middlesex Hospital in Middletown, Connecticut by Dr. Michael G. Johnson. The filter was implanted after receiving a diagnosis of bilateral pulmonary embolism.

115. This Denali® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

116. On or about September 19, 2019, Ms. Napolitano underwent a CT scan in order to evaluate her Denali® Filter at Sound Medical Center in Guilford, Connecticut.Upon information and belief, it was revealed that the Denali® Filter had in fact become tilted 13.6 degrees and the struts of the filter perforated and extended outside of the inferior vena cava wall.Additionally it was found that at least one of the struts comes in close proximity to the small bowel and at least one other strut in close proximity to the aortic bifurcation.

FRADULENT CONCEALMENT

117. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have deprived Plaintiffs of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiffs' part, thus delaying timely filing of Plaintiffs' causes of action.

118. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Bard Filter.

119. Plaintiffs and his healthcare providers could not reasonably have discovered the claims made herein due to Defendants actions.

120. Bard and BPV are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiffs, but instead they concealed them from the Plaintiffs, their healthcare providers, and the public at large. Defendants' conduct, as described in this Petition, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of the Plaintiffs.

CORPORATE/VICARIOUS LIABILITY

121. At all times herein, mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator, and/or joint venture of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiffs.

122. There exists and, at all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by the Plaintiffs. As such, each Defendant is liable to the Plaintiffs for his damages.

123. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling,

inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by the Plaintiffs for his damages.

124. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable case and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiffs.

FIRST CAUSE OF ACTION

NEGLIENCE

125. Plaintiffs re-allege and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

126. At all times relevant to this cause of action, the Defendants Bard, BPV, and DOES 1-100 were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Bard Filter.

127. Defendants designed, manufactured, marketing, inspected, labeled, promoted, distributed, and sold the Bard Filter implanted in Plaintiffs.

128. Defendants had a duty to exercise reasonable and prudent case in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Bard Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

129. Defendants knew or reasonably should have known that the Bard Filter was dangerous or was likely to be dangerous when used in its intended or a reasonably foreseeable manner.

130. At the time of manufacturer and sale of the Bard Filter, Defendants knew or should have known that the Bard Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device; and/or

c. Was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall;

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

131. At the time of manufacture and sale of the Bard Filter, Defendants knew or should have known that using the Bard Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels, organs and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain, mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device, and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

132. Defendants knew or should have reasonably known that consumers of the Bard Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

133. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Bard Filter in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre- and post-sale, Plaintiffs, Plaintiffs' physicians, or the general health care community about the Bard Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre- and post-market testing of the Bard Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Bard Filter;

g. Advertising, marketing, and recommending the use of the Bard Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of its Bard Filter;

h. Representing that the Bard Filter was safe for its intended use when in fact Defendants knew and should have known that the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Bard Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Bard Filter so as to avoid the risk of serious harm associated with the use of the Bard Filter;

k. Advertising, marketing, promoting, and selling the Bard Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Bard Filter.

m. Failing to establish and maintain an adequate post-market surveillance program.

134. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

135. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiffs suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount of be determined at trial.

SECOND CAUSE OF ACTION

STRICT PRODUCT LIABILITY – INFORMATION DEFECT, FAILURE TO WARN

136. Plaintiffs re-allege and incorporates by reference each and every allegation contained in foregoing paragraphs as though fully set forth herein.

137. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Bard Filter, including the one implanted in Plaintiffs, into the stream of commerce and in the course of, directly advertised and marketed the device to consumers or persons responsible for consumers.

138. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed, and sold the Bard Filter, which was implanted in Plaintiffs, the Bard Filter, posed a significant and higher risk than other similar devices of device failure, fracture, migration, tilting, and perforation of the vena cava wall. Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

139. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiffs.

140. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Bard Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

141. No healthcare provider, including those of the Plaintiffs, or patient would have used the device in the intended manner as directed has those facts been made known to the prescribing healthcare providers and/or the ultimate users of the device, including the Plaintiffs.

142. The health risks associated with the Bard Filter as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

143. Plaintiffs and their health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

144. Therefore, the Bard Filter implanted in Plaintiffs was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling, and/or instructions accompanying the product.

145. The Bard Filter implanted in Plaintiffs was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by Defendants.

146. As a direct and proximate result of Defendants' lack of sufficient warning, labeling, and/or instructions, Plaintiffs have suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

THIRD CAUSE OF ACTION

STRICT PRODUCT LIABILITY – DESIGN DEFECT

147. Plaintiffs re-allege and incorporates by reference each and every allegation contained in the foregoing paragraph as though fully set forth herein.

148. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed, and sold into the steam of commerce the Bard Filter, including the one implanted in Plaintiffs.

149. The Bard Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to the Bard Filter implanted in Plaintiffs were reasonably foreseeable to the Defendants.

150. The Bard Filter implanted in Plaintiffs were defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

151. The Bard Filter implanted in Plaintiffs were defective in design, in that its risks of harm exceeded is claimed benefits.

152. Plaintiffs and their healthcare providers used the Bard Filter in a manner that was reasonably foreseeable to Defendants.

153. Neither Plaintiffs, nor their healthcare providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to her implantation with the device.

154. As a direct and proximate result of the Bard Filter's defective design, Plaintiffs have suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

STRICT PRODUCT LIABILITY – MANUFACTURING DEFECT

155. Plaintiffs re-allege and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

156. Prior to, on, and after the date the Bard Filter was implanted in Plaintiffs, Defendants set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Bard Filter for use within the United States.

157. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Bard Filter that was implanted into Plaintiffs.

158. Upon information and belief, the Bard Filter contains manufacturing defects, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line making them inherently unsafe for use by healthcare providers in treating consumers suffering from pulmonary embolism, including the Plaintiffs.

159. Plaintiffs and their healthcare providers used the device in its intended manner or in a manner that was reasonably foreseeable to Defendants.

160. As a result of the manufacturing defects, the Bard Filter injured Plaintiffs and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

161. As a direct and proximate result of the Bard Filter's manufacturing defect, Plaintiffs have suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

162. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

163. At all times relevant to this cause, and as detailed supra, Defendants negligently provided the Plaintiffs, their healthcare providers, and the general medical community, with false of incorrect information, or omitted or failed to disclose material information concerning the Bard Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the Bard Filter

b. The efficacy of the Bard Filter

c. The rate of failure of the Bard Filter

d. The approved uses of the Bard Filter

164. The information distributed by Defendants to the public, the medical community, the Plaintiffs' healthcare providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Bard Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and

warning documents that were included in the packaging of the Bard Filter that was implanted in Plaintiffs.

165. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiffs' healthcare providers; to gain the confidence of the public and the medical community, including Plaintiffs' healthcare providers; to falsely assure them of the quality of the Bard Filter and its fitness for use; and to induce the public and the medical community, including Plaintiffs' healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Bard Filter.

166. The foregoing representations and omissions by Defendants were in fact false. The Bard Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Bard Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiffs suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

167. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiffs and their healthcare providers were induced to, and did use the Bard Filter, thereby causing Plaintiffs to sustain severe and permanent personal injuries.

168. Defendants knew and had reason to know that Plaintiffs, their healthcare providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted the Bard Filter, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

169. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous

injuries and damages to persons who are implanted with the Bard Filter, such as persons like Plaintiffs.

170. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiffs used the Bard Filter, Plaintiffs and their healthcare providers were unaware of said Defendants' negligent misrepresentations and omissions.

171. Plaintiffs, their healthcare providers, and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Bard Filter.

172. Plaintiffs and their healthcare providers reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiffs' injuries as described herein. Plaintiffs have suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PUNITIVE DAMAGES ALLEGATIONS

173. Plaintiff re-allege each and every allegation in this Petition and incorporate each allegation into this Count, as if set forth at length, in its entirety.

174. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

175. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Bard Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

a. Inform or warn Plaintiffs or their health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Bard® Filter from the market

176. Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

177. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiffs implantation with Defendants' defective product, Plaintiffs have suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

DAMAGES

178. Plaintiffs re-allege each and every allegation in this Petition and incorporate each allegation into this Count, as if set forth at length, in its entirety.

179. As a direct and proximate result of the negligent, reckless, and carless conduct of Defendants, Plaintiffs has suffered and will continue to suffer severe injuries which caused him pain, suffering, distress, mental and emotional anguish and anxiety, disfigurement and impairment, a general decrease in his quality and enjoyment of life, all in an amount to be proven at trial.

180. As a further direct and proximate result of the negligent, reckless and careless conduct of Defendants, Plaintiffs have incurred expenses for medical care, and may incur expenses for future medical care, all in an amount to be proven at trial.

181. As a direct and proximate result of the negligent, reckless, and careless conduct of Defendants, Plaintiffs have or may have suffered lost earnings and may suffer future lost earnings and/or diminished earning capacity, all in an amount to be proven at trial.

182. As a further direct and proximate result of the negligent, reckless, and careless conduct of Defendants, Plaintiffs have incurred expenses for driving to doctor appointments, and is

entitled to compensation for her mileage driven to doctor appointments, all in an amount to be proven at trial.

PRAYER FOR RELIEF

183. WHEREFORE, Plaintiffs pray for judgment against Defendants, and each other Defendant named herein, jointly and severally, as follows:

a. For Plaintiffs' general and special damages;

b. For Plaintiffs' expenses incurred for past medical care and future medical treatment of Plaintiffs' injuries;

c. For Plaintiffs' past and future lost wages and loss of earning capacity;

d. For Plaintiffs' expenses driving to doctor's appointments;

e. For Plaintiffs' costs incurred herein;

f. For interest at the highest legal rate on all damages and costs from the time incurred on the date of such judgment, whichever is sooner, until paid; and

g. For such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs request a trial by jury.

DATED this 17th day of March 2020.

/s/ Eric Przybysz

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